

**Remarks:**

Applicant has carefully studied the non-final Examiner's Action mailed 06/29/2004, having a shortened statutory period for response set to expire 09/29/2004, and all references cited therein. The amendment appearing above and these explanatory remarks are believed to be fully responsive to the Action. Accordingly, this important patent application is now believed to be in condition for allowance.

Applicant responds to the outstanding Action by centered headings and numbered paragraphs that correspond to the centered headings and paragraph numbering employed by the Office, to ensure full response on the merits to each finding of the Office.

***Priority***

1. Applicant's claim for the benefit of an earlier filing date stands objected to because the claim recites an incorrect parent application. Accordingly, paragraph [0002] has been amended to recite the correct parent application filing data.

***Specification***

2. The disclosure stands objected to because in paragraph [0008]. --slides-- should be inserted following "on," and because in paragraph [0028], "if" should be --of--. Paragraphs [0008] and [0028] have been corrected as required.

3. Applicant has checked the lengthy specification for other errors and two (2) additional errors were found in paragraphs [0046] and [0078] and are corrected herewith.

***Claim Objections***

4. Claim 1 stands objected to because "means" should be deleted in lines 30, 32-34, 36, and 39. The required deletions are made in claim 1, currently amended.

***Double Patenting***

5. Applicant acknowledges the Office's recitation of the legal status of the non-statutory double patenting rejection.

6. Claim 1 stands rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. patent No. 6,709,408 (Fisher) in view of U.S. patent No. 4,693,257 to Markham. A Terminal Disclaimer to Obviate a Double Patenting Rejection over a Prior Patent is not attached hereto to overcome this ground of rejection because Markham would not have impelled one of ordinary skill to combine the Markham teachings with the teachings of U.S. patent No. 6,709,408.

Markham teaches a tube-in-tube arrangement where a source of fluid is in fluid communication with an elongate space between an outer tube (a guide catheter) and an inner tube (a needle catheter). A normally closed valve is positioned at the distal end of the guide tube. A needle is mounted to the distal end of the needle catheter and a syringe is connected to the proximal end of the needle catheter so that a vacuum is created in the needle catheter when a plunger of the syringe is withdrawn. The needle punches through the valve when the needle catheter is extended in a proximal-to-distal direction. A relatively large (non-cellular level) piece of tissue enters into the lumen of the needle when the needle is advanced in said proximal-to-distal direction. When the needle is retracted to the proximal side of the valve, the valve closes and the fluid in the elongate space flows into the needle catheter under the vacuum caused by retraction of the plunger and carries the collected tissue into the needle. The collected tissue is then taken to a slicing machine where it is sliced and prepared for observation as in all other core biopsy procedures.

Applicant, in sharp, distinct, and patentable contrast, employs no irrigation fluid, no quickly opening and closing normally closed valve, and no core biopsy needle. Applicant's fine needle aspiration biopsy needle collects a cellular level sample when the needle is retracted in a distal-to-proximal direction, which is the opposite of the Markham direction.

It would not have been obvious to one of ordinary skill at the time the present invention was made to modify the invention disclosed in U.S. patent No. 6,709,408 by the Markham teachings. Any obvious aggregation of said two references would merely produce the Markham parts but with the core biopsy needle replaced by a fine needle aspiration biopsy needle. Applicant claims no such structure.

Applicant's invention eliminates: 1) the Markham core biopsy needle; 2) the Markham source of irrigation fluid; 3) the normally closed valve; and 4) the taking of a sample upon extension (as distinguished from retraction) of a needle.

Accordingly, in fairness to Applicant, it cannot be said that Applicant has merely combined the respective teachings of U.S. patent No. 6,709,408 and Markham. Thus, Applicant should not be required to disclaim any part of the term of the patent to be awarded the present invention.

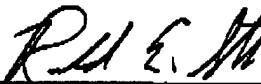
*Conclusion*

7. Applicant agrees that the art made of record and not relied upon is not more pertinent to the claimed invention than the art cited.

8. If the Office is not fully persuaded as to the merits of Applicant's position, or if an Examiner's Amendment would place the pending claims in condition for allowance, a telephone call to the undersigned at (727) 507-8558 is requested. Applicant thanks the Office for its careful examination of this important patent application.

Very respectfully,

SMITH & HOPEN

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Dated: September 24, 2004

pc: John S. Fisher, M.D.

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**CERTIFICATE OF FACSIMILE TRANSMISSION**  
(37 C.F.R. 1.8(a))

I HEREBY CERTIFY that this Amendment A, including Introductory Comments, Amendments to the Specification, Amendments to the Claims and Remarks, is being transmitted by facsimile to the United States Patent and Trademark Office, Art Unit 3736, Attn: Charles Alan Marmor II, (703) 872-9302, on September 24, 2004.

Dated: September 24, 2004



Deborah Preza